

PRESCRIPTION DRUG AFFORDABILITY BOARD MEETING

Monday, March 24, 2025

Minutes

AGENDA ITEM 1

Call Meeting to Order

Chair Van Mitchell called the meeting to order at 2:01 p.m.

Board Members present: Van Mitchell, Gerard Anderson, Ph.D., Eberechukwu Onukwugha, MS, Ph.D., Joseph Levy, Ph.D, Stephen Rockower, MD

AGENDA ITEM 2

Approval of minutes

Chair Mitchell asked for a motion to approve the February 26, 2025 meeting minutes and January 27, 2025 closed session meeting minutes as submitted. Dr. Rockower made the motion, which Dr. Levy seconded, and the Board unanimously approved the minutes.

Action: Minutes APPROVED.

AGENDA ITEM 3

Opportunity for Public Comment

There were four written comments that were shared with the Board and posted to the website. One person registered for an opportunity to provide oral public comment.

Dr. Alankrita Olson, Community to Protect Health, Physician

AGENDA ITEM 4

Cost Review Study

a. Staff Presentation—Cost Review Study Dossier, Sections 1 to 3 Overview (Farxiga)

Executive Director York gave a presentation on the first three sections of the cost review study dossier (to Section 3.2) on Farxiga. Dr. York explained that the dossier is everything that can be considered on a drug when making the affordability determination by the Board and will most likely be seven sections. The following three sections were reviewed in the presentation: background information (information to identify the drug under review), clinical information, and regulatory approval and market context (to Section 3.2). The Board asked questions and provided feedback. This presentation is posted on the Board page of the website.

b. Closed Session—To Consider and Discuss Confidential, Trade Secret and Proprietary Information, under GP § 3-305(b)(13) and HG 21-2c-03(e)(1)(iv) (Farxiga, Jardiance); and to Consult with Counsel and Receive Legal Advice Regarding Proposed Regulations, under GP § 3-305(b)(7).

Having been advised by staff of the inability to consider this item today, Chair Mitchell noted that the first item listed for the closed session, To Consider and Discuss Confidential, Trade Secret and Proprietary Information, under GP § 3-305(b)(13) and HG 21-2c-03(e)(1)(iv) (Farxiga, Jardiance), would not take place at the meeting today.

Chair Mitchell asked for a motion to close the session under General Provisions § 3-305(b)(7), Annotated Code of Maryland, to receive legal advice from counsel and maintain confidentiality and attorney client privilege in closed session.

Dr. Anderson moved to close the session and Dr. Rockower seconded the motion. All Board members voted to close the session; no member opposed the motion. Closed session commenced at 2:42 p.m. via Zoom breakout session.

SUMMARY OF CLOSED SESSION

Pursuant to General Provisions § 3-305(b)(7), Annotated Code of Maryland, on March 24, 2025 at 2:42 p.m. the Board met in closed session to receive legal advice from counsel concerning the proposed regulations and maintain confidentiality and attorney client privilege.

Van Mitchell, Dr. Onukwugha, Dr. Anderson, Dr. Rockower, Dr. Levy, Assistant Attorney General McDonald (counsel), Dr. York (Executive Director), attended the closed session. AAG McDonald provided the Board with legal advice concerning the comments received in response to the proposed action and the proposed amendments to COMAR 14.01.01.01 (Definitions), a proposed new regulation COMAR 14.01.01.06 (Hearing Procedures) and the proposed new chapter COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits). No actions and no votes were taken in the closed session.

AGENDA ITEM 5

Regulations

Proposed Amendments to COMAR 14.01.01.01 (Definitions); new COMAR 14.01.01.06 (Hearing Procedures); new COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

Executive Director York presented Part 2 of the review of comments received by the Board concerning the proposed regulations published in the January 10, 2025 Maryland Register: Proposed Amendments to COMAR 14.01.01.01 (Definitions), New COMAR 14.01.01.06 (Hearing Procedures), and New COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits). At the February 26, 2025 Board meeting, Dr. York presented Part 1 of the review of comments organizing the comments broadly by subject matter. In addition to providing an overview of the comments, the presentation also recommended certain nonsubstantive revisions to the proposed regulations. The Board engaged in some discussion about the comments. The presentation is posted on the Board meeting page of the website.

Chair Mitchell asked for a motion to approve the proposed regulations as revised: Proposed Amendments to COMAR 14.01.01.01 (Definitions); new COMAR 14.01.01.06 (Hearing

Procedures); new COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits). Dr Anderson made the motion and Dr. Rockower seconded. The Board unanimously approved the regulations as submitted and revised.

ACTION: Proposed Amendments to COMAR 14.01.01.01 (Definitions); new COMAR 14.01.01.06 (Hearing Procedures); new COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) as Submitted and Revised APPROVED as Final.

AGENDA ITEM 6

Administrative Update

- Staff will provide an update when the final regulations are published in the Maryland Register.
- The September Board meeting date has been moved to September 15, 2025 and the November Board meeting date has been moved to November 17, 2025.
- The May 19, 2025 Board meeting will be held virtually.
- Two staff position vacancies will be posted in the near future.
- Ms. Shaklee provided a legislative update concerning SB357/HB424- Prescription Drug Affordability Board - Authority for Upper Payment Limits (Lowering Prescription Drug Costs for All Marylanders Now Act), and SB306- Workers' Compensation - Prescription Drug and Pharmaceutical Services - Reimbursements.

AGENDA ITEM 7

Chair's Update

- Chair Mitchell invited the Board members to provide any additional comments.
 - Dr. Anderson proposed an interim Board meeting before the May 19th meeting.
 - Dr. Onukwugha is interested in more patient burden data around Farxiga.
- The next PDASC meeting will be held April 28, 2025, virtually.

AGENDA ITEM 8

Adjournment

Chair Mitchell asked for a motion to adjourn the meeting. Dr. Rockower made a motion to adjourn, which was seconded by Dr. Anderson.

Adjourned at 3:43 PM